

**Amendment and Response**

Applicant: Jack D. Lemmon

Serial No.: 10/688,718

Filed: October 17, 2003

Docket No.: M190.143.101

Title: PROSTHETIC HEART VALVE SIZER ASSEMBLY WITH FLEXIBLE SIZER BODY

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**IN THE CLAIMS**

Please add claim 39.

Please amend claims 1 and 20 as follows:

1.(Currently Amended) A flexible sizer body for evaluating a valve annulus to determine a size of a prosthetic heart valve to be sewn to the valve annulus during heart valve replacement surgery, the prosthetic heart valve including an annular extension having a first flexibility and a sewing ring having a second flexibility, the flexible sizer body comprising:

~~an a continuous~~ outer ring characterized by the absence of a cloth cover; and  
an annular wall coupled to and extending from the outer ring, wherein the annular wall  
forms a plurality of extremities adapted to be inwardly deflected;  
wherein the outer ring defines an undulating, contoured end surface of the sizer body.

2.(Original) The flexible sizer body of claim 1, wherein the annular wall defines a size and a shape substantially similar to a size and a shape of the annular extension of the prosthetic heart valve.

3.(Original) The flexible sizer body of claim 1, wherein the annular extension includes an annular housing.

4.(Withdrawn)The flexible sizer body of claim 1, wherein the annular extension includes a stent.

5.(Withdrawn)The flexible sizer body of claim 4, wherein the annular wall forms a plurality of extremities adapted to selectively deflect inwardly upon the application of an external force.

6.(Withdrawn)The flexible sizer body of claim 5, wherein the selective inward deflection characteristic of the plurality of extremities is substantially similar to a selective inward

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deflection of a plurality of stent posts of the annular extension upon application of the external force.

7.(Withdrawn) The flexible sizer body of claim 4, wherein the annular wall forms a plurality of extremities permanently deflected inwardly.

8.(Previously Presented) The flexible sizer body of claim 1, wherein the annular wall has a flexibility substantially similar to the first flexibility of the annular extension of the prosthetic heart valve and the outer ring has a flexibility substantially similar to the second flexibility of the sewing ring of the prosthetic heart valve.

9.(Original) The flexible sizer body of claim 1, wherein the maximum diameter of the outer ring is substantially similar to a maximum diameter of the sewing ring.

10.(Original) The flexible sizer body of claim 1, wherein the outer ring and the annular wall are each at least partially formed of an elastomeric material.

11.(Original) The flexible sizer body of claim 10, wherein the outer ring and the annular wall are each formed of at least one of the group consisting of santoprene, silicon, and polyurethane.

12.(Original) The flexible sizer body of claim 1, further comprising:  
a handle reception area to selectively receive a handle.

13.(Original) The flexible sizer body of claim 1, further comprising:  
a handle reception area adapted to permanently receive a handle.

14.(Withdrawn) The flexible sizer body of claim 1, further comprising:  
a cylinder sizer extending from the outer ring opposite the annular wall.

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15.(Original) The flexible sizer body of claim 1, wherein the sizer body has a variable flexibility substantially similar to a variable flexibility of the prosthetic heart valve.

16.(Original) The flexible sizer body of claim 15, the flexible sizer body having an overall size and an overall shape substantially similar to an overall size and an overall shape of a corresponding prosthetic heart valve.

17.(Original) The flexible sizer body of claim 1, wherein the flexible sizer body is adapted to interact with the valve annulus in a manner substantially similar to how the corresponding prosthetic heart valve would interact with the valve annulus.

18.(Original) The flexible sizer body of claim 1, wherein the outer ring and the annular wall are both parabolic.

19.(Original) The flexible sizer body of claim 1, wherein the flexible sizer body is sterilizable for reuse.

20.(Currently Amended) A sizer assembly for evaluating a valve annulus to determine a size of a prosthetic heart valve to be sewn to the valve annulus during heart valve replacement surgery, the prosthetic heart valve including an annular extension having a first flexibility and a sewing ring having a second flexibility, the sizer assembly comprising:

a handle defining a first end and a second end; and

a flexible sizer body coupled with the first end of the handle, the flexible sizer body including:

an outer ring characterized by the absence of a cloth cover;

an annular wall coupled to and extending from the outer ring, wherein the annular wall forms a plurality of extremities configured to deflect inwardly;

wherein the extremities define a proximal side of the sizer body;

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wherein the handle extends proximally from the sizer body such that a longitudinal length between the extremities and the second end is less than a longitudinal length between the outer ring and the second end.

21.(Original) The sizer assembly of claim 20, wherein the flexible sizer body further includes:  
a handle reception area adapted to selectively receive the first end of the handle.

22.(Original) The sizer assembly of claim 20, further comprising:  
a cylinder sizer adapted to measure a size of an opening defined by the valve annulus.

23.(Withdrawn) The sizer assembly of claim 22, wherein the cylinder sizer is coupled to and extends from the flexible sizer body opposite the handle.

24.(Original) The sizer assembly of claim 22, wherein the cylinder sizer is selectively coupled to the second end of the handle, the cylinder sizer extending from the handle opposite an extension of the flexible sizer body.

25.(Original) The sizer assembly of claim 20, wherein the outer ring has a flexibility substantially similar to the flexibility of the sewing ring of the prosthetic heart valve.

26.(Original) The sizer assembly of claim 25, wherein the flexible sizer body has a variable flexibility substantially similar to the variable flexibility of the prosthetic heart valve.

27.(Original) The sizer assembly of claim 25, wherein the annular wall forms a plurality of extremities adapted to selectively deflect inwardly upon the application of an external force.

28.(Original) The sizer assembly of claim 27, wherein the plurality of extremities are adapted to be deflected inwardly during insertion of the flexible sizer body into an opening of the valve annulus.

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29.(Withdrawn) The sizer assembly of claim 25, wherein the annular wall forms a plurality of extremities permanently deflected inwardly an amount substantially similar to the amount of inward deflection of a plurality of stent posts of the annular extension upon application of an external force.

30.(Original) The sizer assembly of claim 20, wherein the flexible sizer body is sterilizable for reuse.

31.(Withdrawn) The sizer assembly of claim 20, further comprising:  
at least one representation of a leaflet of the prosthetic heart valve coupled to the flexible sizer body.

32. – 37.(Cancelled)

38.(Previously Presented) A sizer assembly for evaluating a valve annulus to determine a size of a prosthetic heart valve to be sewn to the valve annulus during heart valve replacement surgery, the prosthetic heart valve including an annular extension having a first flexibility and a sewing ring having a second flexibility, the sizer assembly comprising:

- a handle defining a first end, a second end, and a diameter;
- a flexible sizer body coupled with the first end of the handle, the flexible sizer body including:
  - an outer ring characterized by the absence of a cloth cover, and
  - an annular wall coupled to and extending from the outer ring; and
- a cylinder sizer having a diameter substantially similar to an opening defined by the valve annulus, wherein the sizer cylinder is coupled with the second end of the handle.

39.(New) A prosthetic heart valve in combination with a flexible sizer body, the combination comprising:

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a prosthetic heart valve including:

a stent forming a stent ring and stent posts,

a cover encompassing the stent, the cover and the stent combining to define an annular extension,

a sewing ring extending about the stent ring,

a plurality of leaflets, individual ones of which are secured between a respective pair of the stent posts,

wherein the annular extension is characterized by a first flexibility and the sewing ring is characterized by a second flexibility, the first flexibility differing from the second flexibility; and

a flexible sizer body configured in tandem with the prosthetic heart valve, the flexible sizer body including:

an outer ring characterized by the absence of a cloth cover and having a flexibility approximating the second flexibility of the sewing ring,

an annular wall coupled to and extending from the outer ring, the outer wall forming a plurality of extremities corresponding in shape and size with the plurality of stent posts, the annular wall having a flexibility approximating the first flexibility of the annular extension;

wherein the prosthetic heart valve and the flexible sizer body are comprised of different materials.